8 of 100 DOCUMENTS

NOBLE ASSET MANAGEMENT, on behalf of itself and all others similarly situated, Plaintiff, v. ALLOS THERAPEUTICS, INC. and MICHAEL E. HART, Defendants

CIVIL ACTION NO. 04-cv-1030-RPM

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLORADO

2005 U.S. Dist. LEXIS 24452

October 20, 2005, Decided
October 20, 2005, Filed

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff limited liability company (LLC) sued defendants, a pharmaceutical company and its president, on behalf of investors who purchased the company's stock during the period May 29, 2003, through April 30, 2004, alleging securities fraud. Defendants filed a motion to dismiss the LLC's first amended complaint, pursuant to *Fed. R. Civ. P. 12(b)(6)* and the Private Securities Litigation Reform Act.

OVERVIEW: The LLC claimed that the company violated *15 U.S.C.S. § 78j*(b) and *17 C.F.R. § 240.10b-5* when it falsely portrayed the results of clinical trials it was conducting on a drug it developed to treat people who had cancer, thereby creating a perception that the Food and Drug Administration (FDA) would approve the drug, and that the president was liable to investors under *15 U.S.C.S. § 78t*(a) as a controlling person. Defendants denied the claim and they filed a motion to dismiss the LLC's first amended complaint. The court held that (1) it would not take judicial notice of exhibits defendants attached to their motion which were not mentioned in the LLC's complaint, but it would take judicial notice of other exhibits defendants offered; (2) it would not strike pages defendants took from the FDA's website which they attached to their motion; (3) cautionary statements the company made about the approval process were sufficient to inform a reasonable investor about the uncertainties surrounding FDA approval; and (4) because the LLC's claims did not state a violation of *15 U.S.C.S. § 78j*(b), the claim it made against the company's president, pursuant to *15 U.S.C.S. § 78t*(a), also failed.

OUTCOME: The court granted in part and denied in part defendants' request that it take judicial notice of exhibits they attached to their motion to dismiss, denied the LLC's motion to strike three appendices defendants attached to their motion, and granted defendants' motion to dismiss the LLC's first amended complaint, without leave to amend.

LexisNexis(R) Headnotes

Civil Procedure > Pleading & Practice > Defenses, Objections & Demurrers > Motions to Dismiss
Civil Procedure > Pleading & Practice > Motion Practice Generally
[HN1] If a plaintiff does not incorporate by reference or attach a document to its complaint, but the document is referred to in the complaint and is central to the plaintiff's claim, a defendant may submit an indisputably authentic copy to the court to be considered on a motion to dismiss.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act
[HN2] The U.S. Food and Drug Administration may classify a new drug application as "approved," "approvable," or "not approvable." *21 C.F.R. § § 314.105, 314.110*, and *314.120*. The issuance of an approvable letter means that the applicant substantially met the requirements for drug approval. *21 C.F.R. § 314.110(a)*.

Securities Law > Bases for Liability
[HN3] To state a claim for securities fraud under § 10(b) of the Securities Exchange Act of 1934, *15 U.S.C.S. § 78j*(b), and Securities and Exchange Commission Rule 10b-5, *17 C.F.R. § 240.10b-5*, a complaint must contain allegations supporting the following five elements: (1) the defendant made an untrue or misleading statement of

material fact, or failed to state a material fact necessary to make the statements not misleading; (2) the statement complained of was made in connection with the purchase or sale of securities; (3) the defendant acted with scienter, that is, with an intent to defraud or recklessness; (4) the plaintiff relied on the misleading statements, and (5) the plaintiff suffered damages as a result of his reliance.

Civil Procedure > Pleading & Practice > Pleadings > Heightened Pleading Requirements
Securities Law > Bases for Liability
[HN4] A plaintiff bringing a claim for securities fraud under § 10(b) of the Securities Exchange Act of 1934, *15 U.S.C.S. § 78j*(b), on behalf of a class must specify each statement alleged to have been misleading and the reason or reasons why the statement is misleading. *15 U.S.C.S. § 78u-4*(b)(1). *Fed. R. Civ. P. 9(b)* requires that the circumstances constituting fraud be stated with particularity.

Securities Law > Bases for Liability > Deceptive Devices
[HN5] When a plaintiff complains that a defendant failed to disclose a material fact necessary to make its statement not misleading, the concealed information must be information known to the defendant that is not otherwise available to the investing public. Securities laws require issuers to disclose firm-specific information; investors and analysts combine that information with knowledge about the competition, the regulatory conditions, and the economy as a whole to produce a value for stock.

Securities Law > Bases for Liability
[HN6] Fraud-on-the-market theory is based on the premise that publicly available information is reflected in the market price.

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act
Securities Law > Bases for Liability
[HN7] The fact that U.S. Food and Drug Administration (FDA) staff members raise questions does not impose a duty on a pharmaceuticals company to revise its opinion about a drug's efficacy or to report to the public the substance of their conversations with the FDA. Continuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process. Questions may emanate from one or more staffers in random or sporadic fashion. Many, if not all, presumably get answered in the process. Requiring ongoing disclosure of the FDA's questions would not only be disruptive to the review process, it could easily result in misleading the public more than reporting the questions.

Securities Law > Initial Public Offerings & the Securities Act of 1933 > Registration of Securities
[HN8] Under the Private Securities Litigation Reform Act of 1995's safe harbor provision, a defendant shall not be liable with respect to any forward-looking statement that is identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement. *15 U.S.C.S. § 78u-5*(c)(1).

Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act
Securities Law > Initial Public Offerings & the Securities Act of 1933 > Registration of Securities
[HN9] *15 U.S.C.S. § 78u-5*(i)(1) defines the term "forward-looking statement" as (A) a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items; (B) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer; (C) a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by management or in the results of operations included pursuant to the rules and regulations of the Securities Exchange Commission (SEC); (D) any statement of the assumptions underlying or relating to any statement described in § 78u-5(i)(1)(A), (B), or (C); (E) any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or (F) a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the SEC. Projections about the likelihood of U.S. Food and Drug Administration approval are forward-looking statements. They are assumptions related to a company's plan for its product, and as such fall under the Private Securities Litigation Reform Act of 1995's safe harbor rule.

Securities Law > Bases for Liability
[HN10] Interpretations of scientific data are not misleading where the interpretation finds reasonable support in the data. Where a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology of that study. Medical researchers

may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols. The securities laws do not impose a requirement that companies report only information from optimal studies, even if scientists could agree on what is optimal. Nor do they require that companies who report information from imperfect studies include exhaustive disclosures of procedures used, including alternatives that were not utilized and various opinions with respect to the effects of these choices on the interpretation of the outcome data.

Civil Procedure > Pleading & Practice > Defenses, Objections & Demurrers > Motions to Dismiss
Securities Law > Bases for Liability
[HN11] A statement or omission is only material if a reasonable investor would consider it important in determining whether to buy or sell stock. A statement is material if it significantly alters the total mix of information available. Statements of corporate optimism or mere puffing are generally not considered to be material. Such statements are typically forward-looking statements, or generalized statements that are not capable of objective verification. Vague, optimistic statements are not actionable because investors do not rely on them in making investment decisions. Although materiality is a mixed question of law and fact, materiality can be determined on a motion to dismiss. In assessing materiality, the court must consider the context in which the statements were made.

Securities Law > Bases for Liability
[HN12] A complaint alleging securities fraud under § 10(b) of the Securities Exchange Act of 1934, *15 U.S.C.S. § 78j*(b), must state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind. *15 U.S.C.S. § 78u-4*(b)(2). In an action under *15 U.S.C.S. § 78j*(b), the appropriate level of scienter is a mental state embracing intent to deceive, manipulate, or defraud, or recklessness. Conduct is reckless if it amounts to an extreme departure from the standards of ordinary care and presents a danger of misleading buyers or sellers which is either known to the defendant or so obvious that the defendant must have been aware of the danger.

Securities Law > Bases for Liability
[HN13] To satisfy the Private Securities Litigation Reform Act of 1995's pleading requirement with respect to scienter, a plaintiff must plead facts with particularity that, in the overall context of the pleadings, including potentially negative inferences, give rise to a strong inference of scienter. A strong inference of scienter is a conclusion logically based upon particular facts that would convince a reasonable person that the defendant knew a statement was false or misleading.

Securities Law > Bases for Liability
[HN14] Vague information from an unidentified source that does not allege particular facts about conversations, documentary sources, or any other circumstances that would show how the source learned of the information he supposedly possessed is not sufficient to show either the misleading nature of a defendant's statements or to support an inference of scienter. Where a plaintiff does not identify the sources of the facts stated in its complaint, the facts alleged in an information and belief complaint will usually have to be particularly detailed, numerous, plausible, or objectively verifiable by the defendant before they will support a reasonable belief that the defendant's statements were false or misleading.

Evidence > Criminal Evidence > Inferences
Securities Law > Bases for Liability
[HN15] In the absence of allegations of particularized facts about a defendant's actual motives, the fact that a corporation engaged in financing activities during an alleged class period does not create a strong inference of fraudulent intent.

Evidence > Criminal Evidence > Inferences
Securities Law > Bases for Liability
[HN16] In an action alleging securities fraud, a federal district court may consider inferences unfavorable to the plaintiff in determining whether the allegations are sufficient to show scienter.

Civil Procedure > Pleading & Practice > Defenses, Objections & Demurrers > Failure to State a Cause of Action
Securities Law > Bases for Liability
[HN17] To establish a claim for securities fraud under § 10(b) of the Securities Exchange Act of 1934, *15 U.S.C.S. § 78j*(b), and Securities and Exchange Commission Rule 10b-5, *17 C.F.R. § 240.10b-5*, a plaintiff must show reliance. Reliance provides the requisite causal connection between a defendant's misrepresentation and a plaintiff's injury. The doctrine of fraud on the market creates a presumption that the market relied on the defendant's public statements, thus relieving the plaintiff of the burden of proving direct reliance. When a plaintiff alleges the doctrine of fraud on the market, a defendant may rebut any presumption that his statements

artificially inflated the stock price by showing that the alleged misrepresentations did not lead to a distortion of the price. Reliance is not an issue that can be determined under *Fed. R. Civ. P. 12(b)(6)*.

Securities Law > Bases for Liability > Controlling Persons Liability

[HN18] Section 20(a) of the Securities Exchange Act of 1934, *15 U.S.C.S. § 78t*(a), states that every person who, directly or indirectly, controls any person who is liable under any provision of Title 15 of the U.S. Code, or of any rule or regulation thereunder, shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action. To state a prima facie case of control person liability, a plaintiff must establish (1) a primary violation of securities laws, and (2) control over the primary violator by the alleged controlling person.

COUNSEL: [*1] For Noble Asset Management, LLC, on behalf of itself and all others similarly situated, Plaintiff: Darby K. Kennedy, Jeffrey Allen Berens, Robert J. Dyer, III, Dyer & Shuman, LLP, Denver, CO.

For Allos Therapeutics, Inc., Michael E. Hart, Defendants: Paul Howard Schwartz, Cooley Godward, LLP-Colorado, Broomfield, CO; Tara L. Acton, Berenbaum, Weinshienk & Eason, P.C., Denver, CO.

JUDGES: Richard P. Matsch, Senior District Judge.

OPINIONBY: Richard P. Matsch

OPINION:

MEMORANDUM OPINION AND ORDER OF DISMISSAL

Matsch, Senior Judge

Noble Asset Management, L.L.C. (the plaintiff) brought this action for securities fraud on behalf of those who purchased securities of Allos Therapeutics, Inc. (Allos or the Company) during the period from May 29, 2003, through April 30, 2004 (the Class Period). Allos is a Delaware corporation with offices in Westminster, Colorado. It is a biopharmaceutical company focused on developing and commercializing innovative drugs for improving cancer treatments. Allos' stock is listed and traded on the Nasdaq National Market.

One of Allos' lead investigational products is a RSR13, a drug also known as efaproxiral or EFAPROXYN. RSR13 is a synthetic small molecule designed [*2] to increase the level of oxygen in tumor cells for the purpose of increasing the effectiveness of Whole Brain Radiation Treatment (WBRT). (First Am. Compl. PP 3-4). n1 WBRT is a standard treatment for brain metastases, that is, cancer spread to the brain from another primary cancer site.

n1 Paragraph references (P) are to the first amended complaint, unless otherwise noted. This action was commenced on May 19, 2004. The first amended complaint was filed on August 25. 2004.

Pharmaceutical products sold in the United States must be approved by the U.S. Food and Drug Administration (FDA). Clinical trials demonstrating safety and efficacy are required for FDA approval of any new drug product. These trials are conducted in three phases.

In early 2003, Allos completed Phase 3 testing of the effect of RSR13 in combination with WBRT for patients with brain metastases. n2 On April 29, 2003, Allos issued a press release announcing the results of its clinical trials. The press release stated that the tests did not show [*3] that the use of RSR13 resulted in a statistically significant survival advantage in the overall test group, but that the data did show a statistically significant survival benefit for patients with metastatic breast cancer. (PP 45-47). On May 29, 2003, Allos announced that it would proceed with a new drug application (NDA) for RSR13 as a treatment for metastatic breast cancer. (P 52).

n2 *See Nathenson v. Zonagen, 267 F.3d 400, 404 (5th Cir 2001)* (describing Phase 1, 2, and 3 clinical trials). Phase 3 trials test efficacy and safety in an expanded population.

In the first amended complaint, the plaintiff alleges that the press release issued on May 29, 2003, and other statements made by Allos throughout the Class Period falsely portrayed the results of the clinical trials and thereby created a perception in the stock market that the FDA would approve RSR13 in the near future. The plaintiff alleges that the defendants made positive statements about the outcome of the clinical trials, but were aware [*4] that testing protocol rendered the data from those trials inconclusive. The plaintiff claims that the defendants violated § 10(b) of the Securities Exchange Act of 1934, *15 U.S.C. § 78j(b)*, and Rule 10b-5 promulgated thereunder, *17 C.F.R. § 240.10b-5*. The plaintiff also claims that defendant Michael E. Hart is liable as a controlling person under § 20(a) of the Exchange Act,

15 U.S.C. § 78t(a). Mr. Hart was Allos' President, Chief Financial Officer, and Chief Executive Officer throughout the Class Period. (P 20).

On October 2, 2004, the defendants moved pursuant to *Fed. R. Civ. P. 12(b)(6)* and the Private Securities Litigation Reform Act (PSLRA) to dismiss the first amended complaint. n3

> n3 This action is one of six substantially similar class actions that were filed against Allos in May and June 2004. The other five plaintiffs voluntarily dismissed their suits.

The defendants' request for [*5] judicial notice

In connection with their motion to dismiss the first amended complaint, the defendants requested judicial notice of fifteen documents, identified as Exhibits A-O. Exhibits A, B, and C are press releases issued by Allos on May 29, 2003, February 12, 2004, and March 5, 2004. Exhibits D-K are eight analysts' reports about Allos. Exhibit L is a partial transcript of a meeting of the Oncologic Drug Advisory Committee (ODAC), a consulting body to the FDA. n4 Exhibit M is a letter from the FDA to Allos dated May 27, 2004. Exhibit N shows Allos' daily stock prices from April 2003 through May 2004. Exhibit O is an excerpt from the Company's Form 10-K Annual Report for the year ended December 31, 2002, filed with the Securities and Exchange Commission (SEC) in March 2003.

> n4 The complete transcript is available at www.fda.gov/oc/advisory/default.htm.

The plaintiff does not object to judicial notice of Exhibits A, B, C, L, M, N, and O, and the defendants' motion is granted as to those documents. The [*6] plaintiff objects to the defendants' request for judicial notice of the eight analysts' reports, Exhibits D-K.

[HN1] "If a plaintiff does not incorporate by reference or attach a document to its complaint, but the document is referred to in the complaint and is central to the plaintiff's claim, a defendant may submit an indisputably authentic copy to the court to be considered on a motion to dismiss." *GFF Corp. v. Associated Wholesale Grocers, Inc., 130 F.3d 1381, 1384 (10th Cir. 1997)*. The defendants argue that judicial notice is appropriate because the first amended complaint refers generally to analysts' reports in connection with the allegation of fraud-on-the-market. (P 101 (d)). The complaint, however, does not refer to these specific reports, and the source and authenticity of these documents are not apparent. Exhibits D, E, F, G, H, I, J, and K are beyond the scope of the complaint. The defendants' request for judicial notice of them is denied.

The plaintiff's request to strike Appendices A, C, and D to defendants' motion to dismiss

The defendants also submitted four appendices with their motion to dismiss. Appendix A consists of pages from the website of [*7] the FDA's Center for Drug Evaluation and Research (CDER) and includes the CDER's Manual of Policies and Procedures. Appendix B is a copy of an opinion of the United States District Court for the Northern District of California in *Padnes v. Scios Nova Inc., 1996 U.S. Dist. LEXIS 22858, No. C 95-1693 MHP, 1996 WL 539711 (N.D. Cal. Sept. 18, 1996)*. Appendix C consists of pages from the CDER's website and includes a document entitled, "Guidance for Industry E9 Statistical Principles for Clinical Trials." The FDA published it in the Federal Register at *63 Fed. Reg. 49583*. Appendix D consists of pages from the FDA's official website, including an article entitled "Getting Outside Advice for Close Calls," explaining the role of Advisory Committees in the FDA approval process.

The plaintiff moved to strike Appendices A, C, and D, arguing that the defendants did not verify the accuracy and authenticity of these documents and did not show why judicial notice is appropriate. The plaintiff's motion to strike is denied. The plaintiff's fraud claim is premised on the theory that the defendants misrepresented the strength of the Allos NDA by failing to disclose factors that might lead the FDA to reject the [*8] application. Appendices A, C, and D are public documents provided by the FDA relating to its process for reviewing new drug applications and that process is central to an evaluation of the claims made in this case.

Factual chronology

The following statement of facts is based on the allegations of the first amended complaint, and, where noted, the materials submitted by the defendants given judicial notice.

Pre-class period allegations: The Allos press release issued on April 23, 2003

On April 23, 2003, Allos reported the results of its Phase 3 clinical trial of RSR13 in brain metastases. The press release stated:

> While the difference in overall survival between patients who received RSR13 plus whose brain radiation therapy (WBRT) and patients who received only WBRT was not statistically significant, the trial showed a positive survival benefit

among patients with metastatic breast cancer. As in previous clinical trials, the Phase 3 trial also confirmed RSR13's strong safety profile.

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Other key observations from the trial include:

> . Median survival was doubled among eligible patients with metastatic breast cancer who received RSR13 plus WBRT versus [*9] those who received only WBRT (9.00 months vs. 4.47 months . . .). While this subset was not defined as an intent-to-treat subgroup, breast cancer was a pre-specified stratification factor.
>
> . There was a 48 percent increase in median survival among patients in the breast and NSCLC [non small cell lung cancer]intent-to-treat subgroup who were diagnosed with their original cancer before they were diagnosed with brain metastases and who were treated with RSR13 plus WBRT (6.60 months vs. 4.47 months . . .).

(PP 45 -- 47). Allos' stock price fell following this announcement. (P 49). This press release and the corresponding price drop occurred before the commencement of the Class Period.

The putative class period (May 29, 2003 -- April 29, 2004)

In May 2003, Allos had a pre-NDA meeting with the FDA. On May 29, 2003, Allos announced that it would proceed with its NDA for RSR13 for the treatment of brain metastases in patients with breast cancer. (P 52). Allos' May 29 press release repeated the statement in the April 23 press release that breast cancer patients who received RSR13 in the Phase 3 trial achieved a median survival rate nearly twice that of patients receiving [*10] radiation therapy alone. Mr. Hart was quoted as stating that the data observed in patients with metastatic breast cancer was "consistent and compelling." (P 54). On that same day Mr. Hart stated in a conference call, "We are confident in the strength and consistency of the data in the breast cancer subset." (P 55). On May 29, 2003 -- the commencement of the Class Period -- the price of Allos' shares closed at $ 3.75 per share, an increase of $ 1.40 per share (a 60% gain). (P 56).

In June 2003, FDA staff members told Allos that they had concerns about whether the breast cancer subgroup data showed a survival benefit. (P 93). Thereafter, Allos issued press releases describing the results of its clinical trials in positive terms for the breast cancer subgroup and stating that it was pursuing an NDA for RSR13 as a treatment for brain metastases in patients with breast cancer. (PP 58, 59, 61, 62, 64, 66, 68, 71, 72, 77, 79, 81, 82, 83, 84). Allos also filed reports with the SEC in which it described the status of its NDA. (PP 66, 67).

In November 2003, Allos completed a private placement of securities to institutional investors. The Company raised approximately $ 12 million through the [*11] sale of common stock and warrants. (PP 10, 51, 70, 106).

On December 4, 2003, Allos announced that it had completed its NDA submission. (P 72). In February 2004, the FDA accepted Allos' NDA for "priority" review. (P 77). A priority designation is given when "the drug product, if approved, would be a significant improvement compared to marketed products . . . in the treatment, diagnosis, or prevention of a disease." (App. A, at 1). "A priority' designation is intended to direct overall attention and resources to the evaluation of applications for products that have the potential for providing significant preventative or diagnostic therapeutic advance as compared to standard review.'" (*Id.* at 2).

In February 2004, prior to the FDA's completion of its review of Allos' pending NDA, Allos started a second Phase 3 trial focusing on women with brain metastases from breast cancer. (P 104).

In March 2004, Allos filed with the SEC a "shelf registration" to permit the sale of up to $ 75 million in mixed securities. (PP 10, 80, 84). The complaint does not allege that Allos ever sold any shares pursuant to this shelf registration.

In connection with Allos' pending NDA, the FDA sought [*12] the advice of the Oncologic Drug Advisory Committee (ODAC). The ODAC serves as a consulting body to the FDA. *See 21 C.F.R. § 14.1.* Members of the ODAC are not employees of the United States government. (App. D, Ex. L at 206). Such advisory committees provide advice, but do not make decisions on behalf of

the FDA. (Ex. L at 206). A meeting of the ODAC was scheduled for May 3, 2004.

On April 30, 2004, the FDA released a briefing stating the opinion of FDA staff that the "evidence submitted in this application is not convincing and does not support [Allos'] claim of efficacy." (P 86). On April 30, 2004, the price of Allos stock fell to $ 2.55 per share, from its price of $ 4.64 per share on the previous day. (P 87). The end of the Class Period is April 29, 2004.

Post-class period events

On May 3, 2004, the ODAC discussed the data from the Allos clinical trials as support for the efficacy of RSR13 for the subgroup of patients with breast cancer metastatic to the brain. (PP 87-92; Ex. L, at 353). The 17 voting members of the ODAC included oncology doctors, a medical biostatistician, an oncology nurse, and a patient representative. (Ex. L, at 203-206 and [*13] 354). Some committee members voiced opposition to recommending approval, noting that Allos' clinical trials were not originally focused on this specific subgroup. (P 13, Ex. L at 337, 342-43). It was noted, however, that there was a pre-specified subgroup of patients with lung and breast cancer. (Ex. L, at 341). Some committee members opined that the breast cancer subgroup was too small for the data to be reliable and that other factors could explain the positive results in the breast cancer subgroup. (Ex. L, at 346-47). A view favorable to Allos' application was voiced by the committee chairperson, Dr. Donna Przepiorka who stated:

> I was impressed with the fact that there were two trials, albeit not perfectly well designed but two trials with similar results in terms of the magnitude and the direction of the effect, and most strikingly, similar results with regard to outcome. It is very remarkable to see two trials, one right after the other, to have the same median survival in both the control group and the experimental group. I thought that was remarkable.

(Ex. L, at 345-46). The result of that meeting was that the ODAC did not recommend approval of RSR13 for use [*14] with whole brain radiation therapy for patients with breast cancer and brain metastases. (P87). Sixteen members voted against recommending approval. (P 94). Dr. Donna Przepiorka voted in favor of recommending approval. (Ex. L, at 354). n5

n5 Appendix D includes an article about advisory committees entitled "Getting Outside Advice for Close Calls." The court has not drawn any inference from that title about whether the Allos application was a "close call."

On May 27, 2004, the FDA issued a letter to Allos stating, "At this time, substantial evidence of the effectiveness of EFAPROXYN has not been provided." (P 99; Ex. M). The FDA found Allos' NDA to be "approvable." (Ex. M). [HN2] The FDA may classify a new drug application as "approved," "approvable," or "not approvable." *See 21 C.F.R. § 314.105*; *314.110*, and *314.120*. The issuance of an approvable letter means that the applicant "substantially met the requirements" for drug approval. *21 C.F.R. § 314.110(a)*. The [*15] FDA's letter explained that before the application could be approved Allos must complete its second Phase 3 clinical trials on patients with metastatic breast cancer. The FDA's letter stated, "If the study shows effectiveness in this population (increased survival) using the pre-specified analysis, and the study is otherwise satisfactory, we believe it would, together with the subset result in RT-009, support approval." (Ex. M, P 99).

The elements of a claim for securities fraud under § 10(b)

[HN3] To state a claim for securities fraud under *§ 10(b)* of the Exchange Act and *Rule 10b-5*, a complaint must contain allegations supporting the following five elements: "(1) the defendant made an untrue or misleading statement of material fact, or failed to state a material fact necessary to make the statements not misleading; (2) the statement complained of was made in connection with the purchase or sale of securities; (3) the defendant acted with scienter, that is, with an intent to defraud or recklessness; (4) the plaintiff relied on the misleading statements, and (5) the plaintiff suffered damages as a result of his reliance." *Adams v. Kinder-Morgan, Inc., 340 F.3d 1083, 1095 (10th Cir. 2003)*. [*16]

The alleged misleading statements

[HN4] A plaintiff bringing a claim for securities fraud under *§ 10b* of the Exchange Act on behalf of a class must "specify each statement alleged to have been misleading" and "the reason or reasons why the statement is misleading." *15 U.S.C. § 78u-4(b)(1)*. *Fed. R. Civ. P. 9(b)* requires that the circumstances constituting fraud be stated with particularity. The defendants move to dismiss the first amended complaint on the ground that it fails to meet these standards.

The plaintiff asserts that the first amended complaint includes five categories of misleading statements: (1) statements regarding the metastatic breast cancer results;

(2) statements regarding the NDA submission; (3) statements regarding FDA approval; (4) statements regarding the Cox multiple regression analysis, and (5) statements regarding the design of the clinical trials.

Statements about the metastatic breast cancer results

According to the plaintiff, the following are examples of the defendants' misleading statements about the breast cancer subgroup results:

> The data from the breast cancer subset of [*17] patients is from a large randomized Phase 3 study and is overwhelmingly in favor of RSR13 across the entire data set. Breast cancer is a legitimate subset of a predefined intent-to-treat subgroup and was a pre-stratification factor in the trial. (P 55, statement made by Michael Hart during conference call on May 29, 2003).
>
> breast cancer was a pre-specified stratification factor and the results were statistically significant. (P 59, from an Allos press release issued August 7, 2003).
>
> while patients with metastatic breast cancer represent a subset that was not prospectively defined as an intent-to-treat group, breast cancer was a pre-specified stratification factor and the results were statistically significant." (P 6, from Allos Form 10-Q for the third quarter 2003).

(Pl.'s opp'n br. at 16).

The plaintiff does not identify any erroneous data reported by Allos, but complains that the defendants misled investors by putting a positive gloss on the results of the clinical trials for the breast cancer subgroup. When Allos conducted the first Phase 3 trial of RSR13, one intent-to-treat group was an overall group of cancer patients with metastases to the brain. A second [*18] was a subset of patients whose primary cancer was breast or non-small cell lung cancer. (Ex. L, at 341). In its press releases about the result of the Phase 3 clinical trial, Allos announced that the reported survival benefit observed did not reach statistical significance in either of these pre-specified intent-to-treat subgroups. (Ex. B). In their press releases and other statements the defendants described the breast cancer subgroup as a "pre-specified stratification factor."

The plaintiff does not complain that the defendants' description of the breast cancer subgroup as a "pre-specified stratification factor" was false. The plaintiff acknowledges that Allos did in fact disclose that the group of patients with metastatic breast cancer represented a subgroup that was not prospectively defined as an "intent-to-treat" group. The plaintiff explains its position as follows: "The Complaint is not alleging that defendants' statements were false and misleading because they failed to disclose that the breast cancer subgroup was not pre-specified. Rather, the Complaint is alleging that the statements were false and misleading because the defendants failed to disclose that, due to the fact [*19] that the breast cancer subgroup was not defined in advance of the study, the positive results purportedly observed in that subgroup could only be considered as exploratory and could not form the basis for substantive conclusions about the effect of RSR13 on breast cancer patients." (Pl.'s opp'n br. at 16, referring to PP 57(a)-(b)).

This argument must be evaluated within the context of the FDA's guidance documents. (*See* App. C). Included in those documents are standards of the International Conference on Harmonisation (ICH), including "E9 Statistical Principles for Clinical Trials." n6 According to these principles, subgroup analyses are considered exploratory in most cases. (App. C, Statistical Principles at 33-34). The Statistical Principles state, "Any conclusion of treatment efficacy (or lack thereof) or safety based solely on exploratory subgroup analyses is unlikely to be accepted." (*Id.* at 34). The plaintiff argues that the defendants' statements about the breast cancer results were misleading because the defendants failed to disclose this factor.

> n6 The first amended complaint refers to ICH guidelines E3 and E9. (P 57(b)).

[*20]

The fallacy in the plaintiff's argument is that the FDA's policies and the ICH guidelines are public. [HN5] When a plaintiff complains that a defendant failed to disclose a material fact necessary to make its statement not misleading, the concealed information must be information known to the defendants that is not otherwise available to the investing public. "Securities laws require issuers to disclose *firm-specific information*; investors and analysts combine that information with knowledge about the competition, the regulatory conditions, and the economy as a whole to produce a value for stock." *Wielgos v. Commonwealth Edison Co., 892 F.2d 509, 515 (7th Cir. 1989)* (emphasis in original); *In re Exabyte Corp. Sec. Litig., 823 F.Supp. 866, 871-72 (D. Colo. 1993)*. Here the plaintiff alleges fraud-on-the-market.

(PP 101-02). The regulatory environment is presumed to be known in an efficient market. *See Basic Inc. v. Levinson, 485 U.S. 224, 246, 99 L. Ed. 2d 194, 108 S. Ct. 978 (1988)* (explaining that [HN6] fraud-on-the-market theory is based on the premise that publicly available information is reflected in the market price). The public nature of the FDA's guidance documents [*21] must be considered in determining whether the defendants failed to state a material fact necessary to make their statements not misleading. The defendants did not engage in fraud by failing to tell investors about the FDA's published regulatory guidelines and how they might affect the FDA's view of Allos' application. Such information was available to investors.,

Furthermore, the FDA guidelines did not, as the plaintiff suggests, preclude FDA approval. The guidelines state that subgroup analyses are considered exploratory in "most cases" and ordinarily will not provide a basis for definitive conclusions. The safety of RSR13 was not in question, and the subgroup was comprised of patients facing the prospect of imminent death. Allos' application presented a "risk-benefit decision," (Ex. L, at 344), and a possible exception to the general rule.

The plaintiff also alleges that the defendants' positive statements about the clinical trial results were misleading because the defendants did not disclose that the FDA had voiced concerns to Allos in June 2003 about the subgroup analysis. (P 93). This argument is without merit. [HN7] The fact that the FDA staff members raised questions did not impose [*22] a duty upon the defendants to revise their opinions about the drug's efficacy or to report to the public the substance of their conversations with the FDA. *In re MedImmune, Inc. Secs. Litig., 873 F.Supp. 953, 966 (D. Md. 1995)*. "Continuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process. Questions may emanate from one or more staffers in random or sporadic fashion. Many, if not all, presumably get answered in the process. Requiring ongoing disclosure of the FDA's questions would not only be disruptive to the review process; it could easily result in misleading the public more than reporting the questions." *Id.*

Statements regarding the NDA submission

In paragraph 69(b) of the first amended complaint, the plaintiff alleges that the defendants made false and misleading statements in press releases and in the Company's third quarter Form 10Q by stating that the Company had submitted a "rolling NDA for RSR13 as an adjunct to WBRT for the treatment of metastatic breast cancer, and that [it] expected to complete this rolling NDA by December 2003." The plaintiff asserts that Allos created the impression [*23] that FDA approval would be forthcoming in the near future by filing its NDA for RSR13.

Statements regarding FDA approval

The plaintiff alleges that the wording of the May 29 press release, Mr. Hart's comments on that day, and subsequent statements by Allos about the status of its NDA "conditioned investors to believe that it was likely that the FDA would approve RSR13 in the near term." (P 52). In its response brief, the plaintiff argues that the following statements, even if literally true, are actionable because the fostered the impression that FDA approval would be forthcoming:

> The [Company's] decision [to submit a rolling NDA to the FDA to market RSR13 as a treatment for brain metastases from breast cancer] followed a pre-NDA meeting with the FDA in which the preliminary safety and efficacy data from the completed pivotal Phase 3 clinical trial and, specifically, the results in patients with metastatic breast cancer, were reviewed and discussed. (P 59, quote from press release issued August 7, 2003).
>
> We are in ongoing discussions with the FDA regarding the future development of RSR13 as a radiation sensitizer. (P 62, quote from press release issued September 7, 2003). [*24]
>
> The results demonstrated a statistically significant survival benefit in patients with brain metastases from breast cancer. (P 75, quote from Registration Statement /Proxy-Prospectus filed by Allos on January 13, 2004, in connection with a non-registered offering of Allos common stocks and warrants).
>
> We are one step closer to delivering a potential new treatment for patients suffering from brain metastases from breast cancer. (P 77, quote from press release issued February 3, 2004).

(Pl.'s opp'n br. at 19).

Significantly, the plaintiff does not allege that the defendants explicitly assured investors that FDA approval would soon be obtained. The May 29 press release included the following statement:

> This announcement contains forward-looking statements that involve risks and uncertainties. Future events may differ materially from those discussed herein due to a number of factors, including, but not limited to, risks and uncertainties related to the company's ability to adequately demonstrate the safety and efficacy of RSR13 for use as a radiation sensitizer in the treatment of metastatic breast cancer and any other types of cancer, and its ability to obtain [*25] regulatory approval for RSR13, as well as other risks and uncertainties detailed from time to time in the company's SEC filings, including its Annual Report on Form 10-K for the year ended December 31, 2002.

(Ex. A). The risk factors discussed in the Company's 10-K include uncertainty about whether regulatory approval would be forthcoming and whether a second Phase 3 trial might be necessary. (Ex. O, at 15-16).

[HN8] Under the PSLRA's "safe harbor provision,"a defendant "shall not be liable" with respect to any forward-looking statement that is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." *15 U.S.C. § 78u-5(c)(1)*. [HN9] The statute defines the term "forward-looking statement" as follows:

> (**A**) a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;
>
> (**B**) a statement of the plans and objectives of management for future [*26] operations, including plans or objectives relating to the products or services of the issuer;
>
> (**C**) a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission;
>
> (**D**) any statement of the assumptions underlying or relating to any statement described in subparagraph (A). (B), or (C);
>
> (**E**) any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or
>
> (**F**) a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the Commission.

15 U.S.C. § 78u-5(i)(1). Projections about the likelihood of FDA approval are forward-looking statements. They are assumptions related to the Company's plan for its product, and as such fall under the PSLRA's safe harbor rule.

The plaintiff argues Allos' risk disclosures were not sufficient because Allos did not caution investors about the specific risk that [*27] the FDA would not accept its subgroup analyses. The plaintiff's argument overlooks the language of the cautionary statements provided, and it overstates the standard for "meaningful cautionary statements." The Company's cautionary statements addressed the possibilities that test data could be subject to varying interpretations, that the Company might not be able to demonstrate efficacy, that a second Phase 3 trial might be necessary, and that FDA approval might be delayed or not obtained at all. (*See* Ex. M; Ex. O at 15-16). These statements are sufficient to inform a reasonable investor about the uncertainties surrounding FDA approval. Investors who purchased Allos stock during the Class Period had notice that a risk of investing was that the FDA might not approve RSR13 in the near term or ever.

Statements regarding the Cox Multiple Regression Analysis

The plaintiff complains that the defendants made misleading statements about their statistical methodology. "Log-rank analysis" is the primary analytical method approved by the FDA. The Cox multiple regression analysis is another statistical model, but one that was not approved by FDA protocol for Phase 3 clinical trials. In [*28] the May 29 press release, Allos announced that the results of the Phase 3 study based on the primary log-rank analysis were not statistically significant. That press release also stated, "Further analysis of the intent-to-treat data using a Cox multiple regression analysis indicates that RSR13, when combined with WBRT, resulted in a significant 22.5% reduction in risk of death. . . ." Mr. Hart also stated on May 29, 2003:

> When using a Cox analytical model to estimate the treatment effect of RSR13 with the whole brain radiation therapy on survival among all patients, a survival benefit is demonstrated. . . . However, we have elected to focus our NDA submission on the data from metastatic breast cancer patients because of the overall strength and consistency of the data.

(P 54). A press release issued by Allos on November 17, 2003, stated that "the survival benefit for RSR13 was statistically significant in a Cox multiple regression model." (P 68).

The plaintiff argues that the defendants misled investors by describing the analysis of the data under the Cox method. The plaintiff contends that such statements were misleading because they strengthened the Company's representations [*29] about the results for the breast cancer subgroup and contributed to the impression that the FDA would favorably view Allos' NDA for that subgroup. The plaintiff asserts, "defendants caused investors to believe that the FDA must have approved the change from the original log-rank analysis' to the Cox multiple regression analysis.'" (Pl.'s opp'n br. at 20).

This argument has no merit. The plaintiff does not allege that Allos' reported false data or that its Cox analysis was wrong. The defendants did not tell investors that FDA approval was assured. The defendants' statements about the Cox multiple regression analysis were not misleading.

Statements regarding the design of the study

The plaintiff complains that the defendants mischaracterized the test results for the breast cancer subgroup by making positive statements about the study and its design. For example, in paragraph 68 of the first amended complaint, the plaintiff alleges that the defendants made misleading statements in a November 2003 press release. That press release concerned a presentation about the clinical trials for RSR13 given by Dr. John H. Suh of the Brain Tumor Institute of the Cleveland Clinic to the Society [*30] for Neuro-Oncology. The press release stated that a key finding of the trials was that "patients with breast cancer in both the RSR13 and control arms were well matched in terms of prior therapy and subsequent therapy." The plaintiff asserts that this statement was contradicted by data showing that the patients in the RSR13 group received slightly more radiation therapy, chemotherapy and hormonal therapy and were less ill than patients in the control group. (P 88). The November 2003 press release also contained the following statement: "RSR13 significantly improved median survival in all randomized patients with brain metastases when adjusted for imbalances in all pre-specified prognostic factors." (P 68). The plaintiff complains that this statement was fraudulent because the data did not support this conclusion. (P 88). The plaintiff does not allege that the defendants reported false data, but only that the defendants statements about the interpretation of the data were misleading.

[HN10] Interpretations of scientific data are not misleading where the interpretation finds reasonable support in the data. *Padnes, 1996 WL 539711 at *5, 1996 U.S. Dist. LEXIS 22858.*

> Where a company accurately reports [*31] the results of a scientific study, it is under no obligation to second-guess the methodology of that study. Medical researchers may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols. . . . The securities laws do not impose a requirement that companies report only information from optimal studies, even if scientists could agree on what is optimal. Nor do they require that companies who report information from imperfect studies include exhaustive disclosures of procedures used, including alternatives that were not utilized and various opinions with respect to the effects of these choices on the interpretation of the outcome data.

Id. (citing *MedImmune, 873 F.Supp. at 966*). The interpretation of the data from the Allos clinical trials is a matter on which reasonable minds could differ, as shown by the debate within the ODAC. n7 Commenting on Allos' test results, several ODAC members acknowledged that "there was something there." (Ex. L, at 343-44). Dr. Przepiorka, the ODAC chairperson, viewed Allos' data as sufficient to show the efficacy of RSR13 as a treatment [*32] for metastatic breast cancer. The fact that the ODAC ultimately did not recommend approval does not mean that the defendants' statements about the results or design of the study were false. The plaintiff's characterization of the defendants' statements as misleading falls into the category of "fraud by hindsight."

n7 The first amended complaint refers to and quotes from the discussion within the ODAC at P

13 and PP 88-92. The plaintiff did not object to judicial notice of the transcript of the meeting of the ODAC.

Materiality

The plaintiff alleges that the defendants misled the investing public by describing the clinical trial results for the breast cancer subgroup as "compelling," "consistent," "impressive," "significant, "strong" and "positive." (PP 54, 55, 58, 62, 63). The defendants argue that these descriptions are subjective evaluations that are not material and cannot form the basis of a securities fraud complaint.

[HN11] "A statement or omission is only material if a reasonable investor would consider [*33] it important in determining whether to buy or sell stock." *Grossman v. Novell, Inc., 120 F.3d 1112, 1119 (10th Cir. 1997)*. A statement is material if it "significantly altered the total mix' of information available." *Id.* (quoting *TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449, 48 L. Ed. 2d 757, 96 S. Ct. 2126 (1976))*. Statements of "corporate optimism" or "mere puffing" are generally not considered to be material. *Grossman, 120 F.3d at 1119*. Such statements are typically forward-looking statements, or generalized statements that are not capable of objective verification. "Vague, optimistic statements are not actionable because investors do not rely on them in making investment decisions." *Id.*

Although materiality is a "mixed question of law and fact," *TSC Indus., 426 U.S. at 450*, materiality can be determined on a motion to dismiss. In assessing materiality, the court must consider the context in which the statements were made. *Grossman, 120 F.3d at 1121*.

As discussed above, the defendants' positive statements about the clinical trials were made in a context in which the following information was also available to investors: [*34] (1) Allos fully disclosed that the results of it Phase 3 clinical trial showed that the reported survival benefit observed did not reach statistical significance in either of the prospectively defined intent-to-treat subgroups; (2) the FDA's published guidance documents state that subgroup analyses are generally considered to be exploratory and in most cases will not support conclusions about efficacy, and (3) Allos warned investors that it might not be able to demonstrate the efficacy of RSR13 for use as a radiation sensitizer in the treatment of metastatic breast cancer and warned investors that it was uncertain when or whether regulatory approval could be obtained. This context shows that the defendant's positive characterizations of the test results for the breast cancer subgroup were not material in light of the total mix of information available to investors.

Scienter

[HN12] A complaint alleging securities fraud under *§ 10b* of the Exchange Act must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *15 U.S.C. § 78u-4(b)(2)*. In a *§ 10b* action, "the appropriate level of scienter [*35] is a mental state embracing intent to deceive, manipulate, or defraud,' or recklessness." *Kinder-Morgan, 340 F.3d at 1105* (quoting *City of Philadelphia v. Fleming Cos., 264 F.3d 1245, 1259 (10th Cir. 2001))*. Conduct is reckless if it amounts to an extreme departure from the standards of ordinary care and presents a danger of misleading buyers or sellers which is either known to the defendant or so obvious that the defendant must have been aware of the danger. *Fleming, 264 F.3d. at 1260*.

[HN13] To satisfy the PSLRA's pleading requirement with respect to scienter, a plaintiff must plead facts with particularity that, "in the overall context of the pleadings, including potentially negative inferences, give rise to a strong inference of scienter." *Pirraglia v. Novell, Inc., 339 F.3d 1182, 1188 (10th Cir. 2003)*. A strong inference of scienter is "a conclusion logically based upon particular facts that would convince a reasonable person that the defendant knew a statement was false or misleading." *Kinder-Morgan, 340 F.3d at 1105*.

The plaintiff alleges that scienter is shown by the fact that Allos started a second [*36] Phase 3 trial before the FDA acted on its application. (P 104). The plaintiff also alleges that a doctor involved in the RSR13 study did not believe that the Allos NDA would be approved and that he said,"No one he dealt with in the Company believed that it would be approved by the FDA either." (P 105). The plaintiff alleges that the defendants were motivated to cast the clinical trial results in a false light because Allos was depleting its cash supply at a rapid rate and needed to raise capital through a private placement offering. (P 106). Lastly, the plaintiff's response brief alludes to the shelf registration in March 2004 as evidence of the defendants' motive. (P 80; Pl.'s opp'n br. at 29).

None of these allegations supports a fair inference that the defendants' statements were made with the requisite intent The undisputed factual chronology shows that the FDA's response to Allos' application was not a foregone conclusion. Even ODAC members who ultimately voted against recommending approval acknowledged that Allos' data provided some evidence of an increased survival benefit in patients with metastatic breast cancer. (Ex. L, at 335, 337, 343, and 352-53). Allos' commencement [*37] of a second Phase 3 trial in February 2004 does not support an inference that the defendants knew how the FDA would rule on its pending NDA. The FDA did not reject the Allos' application, but rather classified it as "approvable."

Information supplied by the unidentified doctor is too unreliable to be useful to the scienter analysis. The plaintiff has not alleged particular facts about conversations, documentary sources, or any other circumstances that would show how this source learned of the information he supposedly possessed. Such [HN14] vague information from an unidentified source is not sufficient to show either the misleading nature of the defendants' statements or to support an inference of scienter. "Where a plaintiff does not identify the sources of the facts stated in the complaint, the facts alleged in an information and belief complaint will usually have to be particularly detailed, numerous, plausible, or objectively verifiable by the defendant before they will support a reasonable belief that the defendant's statements were false or misleading." *Kinder-Morgan, 340 F.3d at 1103.*

The plaintiff's allegations about the Allos private placement adds little to the [*38] determination of scienter. [HN15] In the absence of allegations of particularized facts about the defendants' actual motives, the fact that a corporation engaged in financing activities during the alleged class period does not create a strong inference of fraudulent intent. *Kinder-Morgan, 340 F.3d at 1104-05*; *Fleming, 264 F.3d at 1269.*

The plaintiff's allegations about the Allos shelf registration in March 2004 are irrelevant. The plaintiff does not allege that Allos ever sold stock pursuant to the shelf registration. The fact that the Company completed a shelf registration during the Class Period does not support the plaintiff's theory that the defendants were motivated to inflate the stock price to keep the Company viable.

[HN16] The court may consider inferences unfavorable to the plaintiff in determining whether the allegations are sufficient to show scienter. *Pirraglia, 339 F.3d at 1187.* Significantly, the FDA classified the Allos NDA as "approvable." In the overall context of the pleadings, the plaintiff's allegations do not give rise to a strong inference of scienter.

Market reliance

[HN17] To establish a claim for securities fraud under [*39] *§ 10(b)* and *Rule 10b-5*, the plaintiff must show reliance. "Reliance provides the requisite causal connection between a defendant's misrepresentation and a plaintiff's injury." *Basic, 485 U.S. at 243.* The doctrine of fraud-on-the-market creates a presumption that the market relied on the defendants' public statements, thus relieving the plaintiff of the burden of proving direct reliance.

When a plaintiff alleges the doctrine of fraud-on-the-market, a defendant may rebut any presumption that his statements artificially inflated the stock price by showing that the alleged misrepresentations did not lead to a distortion of the price. The defendants offered the analysts' reports in Exhibits D-K to show that the plaintiff's fraud-on-the-market theory cannot prevail because the market was aware of the risk the plaintiff claims was concealed. As set forth above, the defendants' argument depends on evidence that is outside the scope of the complaint. Reliance is not an issue that can be determined under *Rule 12(b)(6).*

The § 20 claim against defendant Hart

[HN18] *Section 20(a)* of the Exchange Act states:

> Every person who, directly or indirectly, controls any person [*40] liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). To state a prima facie case of control person liability, "the plaintiff must establish (1) a primary violation of securities laws and (2) control' over the primary violator by the alleged controlling person." *Kinder-Morgan, 340 F.3d at 1107*; *Fleming, 264 F.3d at 1270-71.*

Because the allegations of the first amended complaint are not sufficient to state a primary violation of *§ 10b*, the *§ 20* claim against Mr. Hart also fails.

The plaintiff's request for leave to file a second amended complaint

The plaintiff's brief in opposition to the motion to dismiss the first amended complaint includes a request for leave to file a second amended complaint. (Pl.'s opp'n br. at 38 n.10). At the hearing held on October 11, 2005, the [*41] plaintiff's counsel was unable to identify any new or different factual allegations that would be included in a second amended complaint, if one were permitted. The plaintiff failed to make a proper motion for leave to amend and has not shown why it should be permitted to file yet another complaint.

Based on the foregoing, it is

ORDERED that the defendant's request for judicial notice is granted with respect to Exhibits A, B, C, L, M, N, and O, and denied as to Exhibits D, E, F, G, H, I, J, and K; and it is

FURTHER ORDERED that the plaintiff's motion to strike Appendices A, C, and D is denied, and it is

FURTHER ORDERED that the defendants' motion to dismiss the first amended complaint is granted, without leave to amend.

Dated: October 20th, 2005

BY THE COURT:

Richard P. Matsch, Senior District Judge